Department Of Health
Health Professions Quality Assurance Division
Washington State
Medical Quality Assurance Commission
Policy/Procedure

Title:	**Clinical Guidelines for Office-Based Surgery**	Number: MD 2005-01
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Contact:	**Beverly A. Thomas, Program Manager**	
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Approved		
Chair	**Chelle Moat, MD**	

BACKGROUND:

Over the past 25 years, remarkable advances in anesthesia and medical technology have made surgery outside of hospitals the preferred option for an estimated 70% of all surgeries performed in the United States. Of all outpatient operations, an estimated 20% are performed in physicians' offices prompted by economic and marketing realities. Office-Based surgery (OBS) scheduling is more efficient, patients appreciate convenience, and cost savings can be substantial.

The observed result is a significant volume of surgery being transferred from large, regulated surgical centers to unregulated, small offices. In other states, where the trend has been established for a longer time, untoward incidents of patient harm have prompted formal attempts to regulate OBS either by rule or guidelines. Their concern, which we in Washington share, is for the potential harm to patients when OBS practices are not held to acceptable standards. The Medical Quality Assurance Commission's decision is to develop and issue comprehensive OBS guidelines as a first step in promoting levels of quality and safety for OBS patients comparable to ambulatory surgical centers and hospitals.

GUIDELINES:

These guidelines are intended to be an educational service for those already involved in Office-Based Surgery (OBS) and for physicians contemplating establishment of such a service. Guidelines do provide a valuable service by promulgating a more exact awareness among physicians of OBS standards.

The overriding intent for this effort is to identify and define that which constitutes safe, high quality OBS practice so that allegations of violation and incidents of harm to patients can be kept to a minimum.

A. Application

These guidelines apply to physicians practicing in office settings located outside hospitals and ambulatory surgical centers that perform office-based surgery (OBS) employing one or more of the following levels of sedation, analgesia, and general anesthesia:

- Moderate sedation/analgesia.
- General anesthesia.
- Major conduction anesthesia.
- Infiltration for tumescent liposuction.

B. Definitions

1) **Office-based surgery (OBS):** Any surgical or other invasive procedure requiring anesthesia, analgesia or sedation including cryosurgery, laser surgery, and high volume liposuction which is performed in a location other than a hospital or ambulatory surgical center and which results in a patient stay of less than 24 hours.

2) **Physical status classification:** Provided by the American Society of Anesthesiologists (ASA) to describe the physical status of patients by degree of anesthesia risk:

   I—Normal, healthy patient;

   II—Mild systemic disease;

   III—Severe systemic disease limiting activity but not incapacitating;

   IV—Incapacitating disease that is a constant threat to life.

3) **Level 1—Minimal Sedation (anxiolysis):** a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected.

4) **Level 2—Conscious Sedation/Analgesia:** A minimally depressed level of consciousness that retains the patient's ability to independently and continuously maintain an open airway, a regular breathing pattern, protective reflexes and respond purposefully and rationally to tactile stimulation and verbal command.

5) **Level 3—Deep Sedation/Analgesia:** A drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

6) **Level 3—General Anesthesia:** A drug-induced loss of consciousness during which patients cannot be aroused, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. The patient often requires assistance in maintaining a patent airway, and positive pressure ventilation may be required because

of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

7) **Level 3—Major Conduction Anesthesia:** Administration of a drug or combination of drugs to interrupt nerve impulses without loss of consciousness including: epidural, caudal, spinal, axillary, stellate ganglion blocks, and brachial anesthesia. Major conduction anesthesia does not include digital or pudendal blocks.

8) **Tumescent Liposuction:** Liposuction involving the subcutaneous infusion of a solution containing a local anesthetic drug in varied combinations with other medications, followed by aspiration of fat through cannulas.

9) **Monitoring:** The continual clinical observation of a patient and the use of instruments to measure, display and record the values of certain physiologic variables such as pulse, oxygen saturation, level of consciousness, blood pressure and respiration.

10) **Complications:** Untoward events occurring at any time within 30 days of any surgery, special procedure or the administration of anesthesia in an office setting including, but not limited to, any of the following: paralysis; malignant hyperthermia; seizures; myocardial infarction; renal failure; significant cardiac events; respiratory arrest; aspiration of gastric contents; cerebral vascular accident; transfusion reaction; pneumothorax; allergic reaction to anesthesia; critical equipment failure; unintended hospital admission longer than 24 hours; or death.

C. Administration

1) **Governance:** Physicians practicing in an OBS setting practice should adopt policies describing the organizational structure of the practice, including lines of authority, responsibilities, accountability and supervision of personnel. All OBS practices should have a medical director or governing body that establishes policy and is responsible for the activities of the facility and its staff. In solo practices, the physician may serve in this capacity. Administrative policies should be implemented to provide quality health care appropriate for the type of procedures performed. Policies and procedures governing the orderly conduct of the facility should be in writing and should be reviewed annually. All applicable state and federal laws and regulations, local laws and codes must be observed.

2) **National Accreditation:** Accreditation by a nationally recognized organization is evidence that an OBS practice has been inspected and certified to meet established national standards. Many states make accreditation a requirement. For Washington guidelines, accreditation is strongly encouraged. Among acceptable agencies are: the American Association for Accreditation of Ambulatory Surgical Facilities (AAAASF); Accreditation Association for Ambulatory Health Care (AAAHC); the Joint Commission on Accreditation of Healthcare Organizations (JCAHO); and Medicare Certification.

3) **Emergency Care and Transfer Plan:** A physician practicing in an OBS setting should ensure written policies are in place to ensure the necessary personnel, equipment, and procedures to handle medical and other emergencies that may be reasonably anticipated to arise in connection with services provided. At a minimum, there should be written

protocols for handling emergency situations, including medical emergencies and internal and external disasters. All personnel should be appropriately trained in emergency protocols. Adequate equipment for cardiopulmonary resuscitation should be immediately available. There should be written protocols in place for the timely and safe transfer of patients to a pre-specified alternate care facility within a reasonable proximity when extended or emergency services are needed. Protocols should include a written transfer agreement with a reasonably convenient hospital.

4) **Personnel:** All health care practitioners should have appropriate licensure or certification and the necessary training and skills to deliver the services provided by the facility. All personnel assisting in the provision of health care services must be appropriately trained, qualified and supervised and sufficient in number to provide appropriate care. Functional responsibilities of all health care practitioners and personnel should be defined and delineated. Policies and procedures for oversight of health care practitioners and personnel should be in place. Clinical information relevant to patient care should be kept confidential and secure. At least one person with training in advanced resuscitative techniques (e.g. Advanced Cardiac Life Support (ACLS) or Pediatric Advanced Life Support (PALS)) should be immediately available until all patients are discharged. All medical personnel should maintain training in basic cardiopulmonary resuscitation at a minimum.

5) **Credentialing:** The physician should ensure that credentials, including delineation of privileges, of all health care practitioners are established by written policy, and are periodically verified and maintained on file.

6) **Acceptable Credentials for Professional Staff:**

   - State licensure;
   - Procedure specific education, training, experience, and successful evaluation appropriate for the patient population (e.g. pediatrics);
   - For physicians, board certification or completion of training programs leading to certification;
   - For non physicians, certification that is appropriate and applicable for the practitioner's scope of practice;
   - Professional misconduct and malpractice history;
   - Participation in peer and quality review;
   - Participation in continuing education;
   - Malpractice insurance coverage;
   - Procedure specific competence relating to professional society standards, nationally recognized accreditation, and proctored training in new procedures in accordance with professional society standards and guidelines.

7) **Unlicensed personnel:** The physician should ensure that unlicensed personnel are not assigned duties or responsibilities that require professional licensure. Duties that do not require professional licensure assigned to unlicensed personnel should be in accordance

with their training, education and experience under the direct supervision of a practitioner.

8) **Medical Records:** The physician should ensure that legible, complete, comprehensive, and accurate medical records are maintained for each patient. The medical record should include a recent history, physical examination, and any pertinent progress notes, operative reports, laboratory reports and x-ray reports, as well as a record of written and oral communications with other medical personnel. Records should highlight allergies and untoward drug reactions. Specific policies should be established to address retention of active records, retirement of inactive records, timely entry of data in records and release of information contained in records.

   All information relevant to a patient should be readily available to authorized health care practitioners any time the office facility is open to patients or in the event that a patient is transferred due to surgical complications. Patient information should be treated as confidential and protected from loss, tampering, alteration, destruction and unauthorized or inadvertent disclosure in accordance with state and federal law. Records should be organized in a consistent manner that facilitates continuity of care. Discussions with patients concerning the necessity, appropriateness, and risks of proposed surgery, as well as discussion of treatment alternatives, should be documented in a patient's medical record along with documentation of executed informed consent.

9) **Patients Rights:** The physician should ensure that patients are treated with respect, consideration and dignity. The physician should ensure that all applicable patient rights and benefits under the law are honored, including but not limited to:

   - their right to access their medical records and health care information according to RCW 70.02,
   - their right to privacy and confidentiality according to state and federal laws,
   - their right, when not contra-indicated, to participate in the decisions about their health care,
   - their right to refuse diagnostic procedures, treatment, and prescribed medications, and
   - their right to be advised of the consequences of their refusal.

10) **Maintenance of Surgical/Anesthesia Equipment:** The physician should ensure that all surgical and anesthesia equipment and machines are regularly maintained and inspected consistent with manufacturer recommendation. A record of such maintenance should be retained. Equipment should be of a quality and age comparable to that of hospital and ambulatory surgical centers.

11) **Infection Control:** The physician should ensure that the OBS practice implements policies for infection control that promote an aseptic environment and minimize the potential for cross-contamination. The policies should be consistent with generally accepted standards of infection control for operating rooms and adjacent spaces.

12) **Data Collection:** OBS practice data should be collected in a reportable format. To be included are participation data for principal physicians, surgeons and anesthesiologists,

and Certified Registered Nurse Anesthetists (CRNA). The data should list numbers and types of procedures and reflect surgical as well as anesthesia outcome experience of the practice and be suitable for comparison to other similar OBS practices.

13) **Reportable incidents:** OBS practices should record significant unintended incidents. Incidents should include, but are not limited to:

- death of a patient within 24 hours of surgery;
- admission of a patient to another facility within 24 hours for treatment of complications of surgery or anesthesia;
- bleeding episodes requiring transfusion within 24 hours of surgery;
- life-threatening cardiorespiratory events and;
- anaphylaxis or other serious adverse drug reaction;
- critical equipment failure.

14) **Performance Improvement:** The physician practicing in an OBS setting should ensure that a performance improvement program is implemented to provide a mechanism for periodic review (minimum of every six months) of the current practice activities and quality of care provided to patients. Included in the system should be a mechanism of Peer Review by OBS physicians who are not affiliated with the same practice. Commonly used system choices are:

- cooperative agreement with a hospital-based peer review program;
- cooperative agreement with other practices for joint assessment;
- cooperative agreement with other specialty oriented review entities.

D. Clinical

Patient Evaluation: The surgeon practicing in an OBS setting, or his/her designee, should perform a history and physical examination. The history should be current and reassessed by the surgeon on the day of the procedure. Pre-operative evaluation should consist of reviewing the patient history; conducting a physical exam; providing for diagnostic testing and specialist consultation; developing a plan of perioperative care; acquainting the patient, responsible or designated party; or surrogate decision maker with the proposed plan, and discussing the risks and benefits of the surgery and alternative methods or treatments. Intra-operative evaluation should include continuous clinical observation and vigilant monitoring. Careful consideration and appropriate pediatric consultation should be given prior to providing services to infants and children.

1) **Discharge evaluation:** The physician practicing in an OBS setting should ensure that at least one person with training in advanced resuscitative techniques, (e.g., ACLS or PALS), should be immediately available until all patients are discharged. No patient should be discharged until a qualified practitioner determines the patient is adequately recovered from anesthesia and the surgical procedure. Documentation of evaluation for discharge should be noted in the health record. Criteria for discharge of all patients who have received anesthesia should include:

- A determination that the patient has stable vital signs;
- Return to pre-procedure mental status;
- Ambulates without dizziness if ambulation is expected;
- Has minimal bleeding, pain, nausea and vomiting;
- Discharge in the company of a responsible adult.

2) **Patient Instruction:** Verbal instructions understandable to the patient along with written instructions should be provided at discharge. Instructions should include:

- The name of the responsible practitioner;
- The procedure performed;
- Information about complications that may arise;
- Telephone numbers to use in case of complications or questions;
- Instructions for medications; and
- Date, time and place for follow up visits.

E. Anesthesia

Levels of Sedation and Analgesia

The continuum of sedation and analgesia has been separated into Levels, based on the American Society of Anesthesiology (ASA) document, *"Continuum of Depth of Sedation, Definition of General Anesthesia and Levels of Sedation/Analgesia."* See definitions B3 to B7.

1) **Level 1** Minimal Sedation (anxiolysis);
2) **Level 2** Moderate Sedation/Analgesia (conscious sedation);
3) **Level 3** Deep Sedation/analgesia (conscious sedation); Major Conduction Anesthesia; and General Anesthesia

Level 2 and Level 3 Skill Requirements

The physician practicing in an OBS setting should ensure that all health care practitioners who administer anesthesia should be licensed, qualified, and working within his/her scope of practice. Such practitioners, (anesthesiologist, Certified Registered Nurse Anesthetist, Registered Nurse (RNs) or Physician Assistants (PAs), should maintain current training in Advanced Cardiac Life Support (ACLS) for adult patients and Pediatric Advanced Life Support (PALS) for pediatric patients.

Physicians who perform procedures utilizing Level 2 or 3 anesthesias should maintain current training in ACLS for adult patients and PALS for pediatric patients. All health care professionals, at a minimum, should maintain training in basic life support (BLS) for cardiopulmonary resuscitation

At least one person with ACLS training for adult patients and PALS training for pediatric patients should be immediately available until all patients are discharged.

Anesthesia Qualifications

1) Anesthesiologist qualifications should include verifiable completion of specialty training and a record of credentialed hospital experience.

2) CRNA qualifications should include completion of an accredited nurse anesthesia course.

3) Registered Nurses (RNs) and Physician Assistants (PAs) are to follow protocols for administration of sedation for Level 2 conscious sedation. The Washington Anesthesiology Society recognizes authorized CME courses or equivalents as suitable training for RNs or PAs for conscious sedation. RNs and PAs intending to produce a given level of sedation should be able to rescue patients whose level of sedation becomes deeper than intended.

4) Anesthesia Working Agreements with Medical Directors: OBS physicians should have common agreements with anesthesia providers so that important aspects of providing anesthesia are understood:

5) Anesthesia providers will develop plans for anesthesia and acquaint the patient or responsible adults with the proposed plans.

6) The quality of anesthesia machines and other equipment is to be comparable to that of hospital and ambulatory surgical centers.

7) There is a reliable source of oxygen, suction, resuscitation equipment and emergency drugs.

8) Emergency power back up is available.

9) Sufficient space is available to accommodate all necessary equipment and personnel and to allow for expeditious access to patient, anesthesia machine (when present) and all monitoring equipment.

10) Facilities comply with all applicable federal, state, and local laws and regulations pertaining to fire prevention and other safety issues.

11) Anesthesia providers are satisfied with competency levels of medical personnel assisting in the operating room and recovery area.

12) Patients at high risk of complications (Level 3 or 4) will not be accepted for scheduling and will be referred to a hospital or ambulatory surgical center.

13) Special evaluation and consideration should be exercised to justify anesthetics and surgery for patients less than 4 years old. Providers of general anesthetics to infants and children should have demonstrated competency for pediatric anesthesia and should adhere to specialty standards in selecting OBS settings for pediatric surgery and anesthesia. Anesthesiologists who were consulted for this document recommend preoperative evaluation by a qualified physician and written justification by the surgeon for patients less than 4 years old.

Guidelines for Post-Anesthesia Care [1]

All patients who have received general anesthesia, major regional anesthesia or sedation/analgesia should receive appropriate post-anesthesia management:

1) Space should be designated and properly equipped for appropriate observation and monitoring prior to discharge.
2) The medical aspects of care in the Post Anesthesia Care Unit (PACU) should be governed by policies and procedures approved by the medical director or governing body.
3) The patient should be observed and monitored by methods appropriate to the patient's medical condition. Particular attention should be given to monitoring oxygenation, ventilation, circulation and temperature. A quantitative method of assessing oxygenation such as pulse oximetry should be employed in the initial phase of recovery.
4) An accurate recovery record should be maintained and sent with the patient in the event of emergency transfer.

Guidelines For Basic Anesthetic Monitoring:

1) Qualified anesthesia personnel should be present in the room throughout the conduct of all general anesthetics, regional anesthetics and monitored care.
2) During all anesthetics, oxygenation, ventilation, circulation, and temperature should be continually evaluated using systems and equipment comparable to hospital and ambulatory care centers.
3) Every patient receiving anesthesia should have temperature monitored.
4) Anesthesia providers should not participate as surgical assistants.
5) The facility should have equipment available and written protocols to quickly obtain medications to treat malignant hyperthermia when triggering anesthetic agents are used.

F. Miscellany

Liposuction: Liposuction procedures should be performed by physicians with appropriate training following national professional association guidelines. Procedures provided should be within the scope of practice of the health care practitioner and capabilities of the facility. Because Liposuction techniques have been evolving rapidly, practitioners will be responsible for keeping their procedures consistent with current specialty guidelines.

ACKNOWLEDGEMENTS
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[1] Headings taken from, Guidelines of the Washington State Medical Association *Office-based Anesthesia (5/13/2001)*